

Application No. 10/054,093
Amendment dated June 12, 2006
Reply to Office Action of February 10, 2006

Docket No.: HO-P02206US0

REMARKS

Claims 1-3, 5-12 and 14-17 are pending. Claims 4 and 13 have been canceled without acquiescence and without prejudice. Claims 18-57 were canceled in the Response to Restriction Requirement filed January 17, 2006 in that they were drawn to a non-elected invention. Claims 1 and 12 have been amended without acquiescence and without prejudice to clarify the invention. Support for these amendments can be found in the original claims 4 and 13. Applicants assert that no new matter has been added. Applicants retain the right to file any continuation and/or divisional application to any canceled subject matter. The outstanding issues of this Office Action are:

- Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable in view of co-pending US Application Nos. 10/264,886 and 10/891,895.
- Claims 1-4, 9-13 and 17 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Hand et al. (US 5,431,927).
- Claims 1-17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hand et al. in view of Cunningham (Archer Daniels Midland forms joint venture to produce fat-fighting oil. Archer Daniel Midland Company: News Release, June 13, 2001).

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Rejection under Provisional Double Patenting

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable in view of co-pending US Application Nos. 10/264,886 and 10/891,895. Applicants traverse.

The Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated: "Once the provisional rejection has been made, there is nothing the

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examiner and the applicant must do until the other application issues." *In re Mott*, 190 U.S.P.Q. 536, 541 (C.C.P.A. 1976) (emphasis added). M.P.E.P. § 804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such a provisional rejection until one of the applications issues as a patent.

Thus, Applicants request that this rejection be held in abeyance until the conflicting claims are in fact patented.

II. Rejection under 35 U.S.C. 102b

Claims 1-4, 9-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hand et al. (US 5,431,927). Applicants traverse.

In order to advance the prosecution of the present invention, Applicants have amended independent claims 1 and 13 to indicate that the functional ingredient is L-carnitine, conjugated linoleic acid or a diacylglyceride. The Examiner admits on page 4 of the Office Action that Hand et al. does not teach diacylglyceride. However, the Examiner surmises that because Hand et al. teaches soy oil which contains long-chain fatty acids such as linoleic acid that Hand et al. teaches conjugated linoleic acid. Applicants assert that linoleic acid and conjugated linoleic acid are two different compounds having different purposes. Linoleic acid is an unsaturated omega-6 fatty acid. Linoleic acid has two *cis* double bonds located at positions 9 and 12 (See definition from http://en.wikipedia.org/wiki/Linoleic_acid). Conjugated linoleic acid is structurally different than linoleic acid, for example, conjugated linoleic acid (CLA) have double bonds at positions, for example, 9 and 11 and 10 and 12 (See definition from http://en.wikipedia.org/wiki/Conjugated_Linoleic_acid). The unique chemical structure of CLA has two double bonds separated by one single bond. This is not the same chemical structure as linoleic acid. Thus, Hand et al. does not teach conjugated linoleic acid; Hand et al. teaches linoleic acid which is not the same as conjugated linoleic acid as presently claimed. Further, the pet food product taught by Hand et al. is a product that is used for the reduction in plaque and teeth cleaning, not to promote weight management.

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In view of the pending independent claims 1 and 13, Applicants assert that Hand et al. does not teach each and every element. Nowhere that the Applicants can identify is there any teaching of L-carnitine, conjugated linoleic acid or a diacylglyceride as a functional ingredient in the pet food taught by Hand et al. If the Examiner continues to maintain Hand et al. as the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in Hand et al. *See, In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

In view of the above, Applicants request that the rejection be withdrawn.

III. Rejection under 35 U.S.C. 103a

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hand et al. in view of Cunningham (Archer Daniels Midland forms joint venture to produce fat-fighting oil. Archer Daniel Midland Company: News Release, June 13, 2001).

Applicants assert that the present references relied upon by the Examiner clearly fail to establish a *prima facie* case of obviousness. More particularly, the Examiner has not established the motivation to combine Hand et al. with Cunningham. Applicants assert that neither of these references teach or suggest the pet food product of the present invention.

Turing to references, Hand et al. teaches a pet food product that has a function of improving tooth cleansing and reducing plaque. Nowhere that Applicants can find is there any mention or suggestion of the pet food product taught in Hand et al. as a pet food product that can be used to promote weight management nor any level of use of the ingredients in a pet food product to promote weight management. As the Examiner has indicated Hand et al. does not teach or suggest the use of diacylglyceride as a functional ingredient. Cunningham is a News Release that mentions that diacylglyceride can be used for weight loss. However, nowhere in Cunningham is there any mention or suggestion of adding diacylglyceride or diacylglycerol (DAG) to pet food product nor is there any mention nor suggestion of how to produce a pet food product containing diacylglyceride or diacylglycerol (DAG), for example, there is no mention or suggestion of the usage level of DAG in any product let alone a pet food product.

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Thus, according to *In re Hoeksema*, 399 F.2d 269, 274-75, 158 USPQ 597, 601 (CCPA 1968):

If the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on the close relationships between their structures and those of prior art compounds.

Also, *In re Hoeksema* states: [if] there is no showing of a known or obvious way to manufacture [the compound]...it seems to us that the "invention as a whole," which section 103 demands that we consider, is not obvious from the prior art of record.

Furthermore, Applicants maintain that the Examiner has not established a *prima facie* case of obviousness. The person of ordinary skill in the art is an objective legal construct presumed to think along conventional lines without undertaking to innovate, whether by systematic research or by extraordinary insights. *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 56 U.S.P.Q.2d 1186 (Fed. Cir. 2000), citing *The Standard Oil Co. v. American Cyanamid Company*, 774 F.2d 448, 227 U.S.P.Q. 293 (Fed. Cir. 1985), which states the following:

The statutory emphasis is on a person of ordinary skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something--call it what you will--which sets them apart from the workers of ordinary skill, and one should not go about determining obviousness under § 103 by inquiring into what patentees (i.e., inventors) would have known or would likely have done, faced with the revelations of references. A person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which (emphasis added).

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Even if one of skill in the art had motivation to combine the ingredients in the compositions of Hand et al. and Cunningham, there is no motivation to alter the compositions that would result in a pet food product that would promote weight management. On at least page 6 of the Action, the Examiner surmises that one of skill in the art would have been motivated to combine the ingredients of the references to result in the claimed composition. Other than being taught the combination of ingredients in the present Specification to achieve the pet food product, Applicants assert that the references on a whole or separately do not provide enough information to produce the claimed invention. Hand et al. does not mention a pet food that can be used to promote weight management. Hand et al. may mention some of the main ingredients of the claimed invention, however, these ingredients in Hand et al. are not mixed to form a pet food product that promotes weight management, nor is there any suggestion to form a pet food product that promotes weight management. Cunningham does not remedy this defect. The Examiner surmises that one of skill in the art would be able to take the ingredients identified in Hand et al. and Cunningham and combine them in such a manner to produce the claimed invention. Cunningham may mention that DAG has promising results in lowering fat in humans, but there is mention or suggestion that DAG would work in domesticated animals. Applicants assert that as noted in MPEP 2144.03 and in keeping with *In re Zurko* (258 F.3d 1385, 59 USPQ2d 1697 (Fed. Cir. 2001)), an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support, and the Examiner has provided no evidentiary support for the assertion that one of skill in the art would be motivated to produce the pet food product of the presently claimed invention. The Examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. *In re Chevenard*, 139 F.2d 713, 60 USPQ 241 (CCPA 1943). *In re Soli*, 317 F. 2d 941, 945-946, 137 USPQ 797, 800 (CCPA 1963), and the Examiner has failed to do this. Moreover, if the Applicant adequately traverses the Examiner's assertion of official notice, the Examiner must provide documentary evidence in the next Office Action if the rejection is to be maintained. See 37 CFR §1.104 (c)(2) and *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697. If the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR §1.104(d)(2).

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Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art, are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record that may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)) (emphasis added).

Furthermore, Applicants respectfully remind the Examiner that section 103 requires consideration of the claimed invention "as a whole." This "as a whole" requirement prevents evaluation of the invention part by part, in hindsight. *Envil. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983). Without this requirement, an obviousness assessment could break an invention into its component parts, then find a prior art reference containing the component parts, and on that basis alone declare the invention obvious. The courts have refused to act on this type of hindsight reasoning, which uses the invention as a roadmap to find its prior art components. This type of analysis discounts the value of novel selection inventions. Thus, the courts have required that an Examiner must show some suggestion or motivation, excluding the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Lee* 277 F. 2d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); and *c.f. Ruiz v. A.B. Chance Co.*, F.3d 1270 (Fed. Cir. 2004).

Again, there must be some suggestion or motivation to combine these particular references to achieve Applicants' novel and non-obvious invention. Applicants remind the Examiner that the level of skill in the art cannot be relied upon to provide the suggestion to combine references. See *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). If the Examiner maintains the rejection, the courts have required that the Examiner show some suggestion or motivation, excluding the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Lee* 277 F. 2d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); and *c.f. Ruiz v. A.B. Chance Co.*, F.3d 1270 (Fed. Cir. 2004). Even though Cunningham does not teach or suggest the presently claimed pet food composition, it also do not provide any reason to be combined with Hand et al. to produce the presently claimed invention.

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In addition to the lack of motivation to combine, Applicants reiterate that the Examiner has not provided a clear reason for expectation of success as required to establish a *prima facie* case of obviousness. See *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991). Since Hand et al. does not teach a pet food product that can be used to promote weight management and Cunningham does not teach that DAG can be added to a pet food production, Applicants assert that there is no expectation of success to add DAG taught in Cunningham to the pet food product taught in Hand et al.

Thus, in view of the above arguments and presently amended claims, Applicants respectfully request that the rejection be withdrawn.

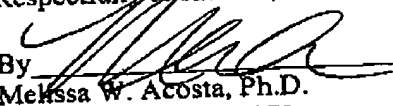
CONCLUSION

In view of the above, applicant believes the pending application is in condition for allowance. If the Examiner believes that there are any outstanding issues, the Examiner is requested to contact the below undersigned for a quick resolution.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02206US0 from which the undersigned is authorized to draw.

Dated: June 12, 2006

Respectfully submitted,

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Conjugated linoleic acid - Wikipedia, the free encyclopedia

Conjugated linoleic acid

From Wikipedia, the free encyclopedia
(Redirected from Conjugated Linoleic Acid)

Conjugated linoleic acid (CLA) refers to a family of eight geometric isomers of linoleic acid, which is found preferentially in dairy products and meat.

Conjugated linoleic acid is a trans fat, though some researchers claim that it is less harmful than other trans fatty acids. CLA is a Conjugated system, and the trans linkages are not counted as trans fat for the purposes of nutritional regulations and labeling.

CLA comes in two isomers, the 9,11 isomer which appears responsible for improving muscle growth and the 10,12 isomer which primarily prevents lipogenesis (storage of fat in adipose tissue). Most supplements sold in stores contain a 50/50 mix of both isomers. [1]

Various antioxidant and antitumor properties have been attributed to CLA, and studies on mice and rats show promising results, however it is suspected that sufficient concentrations to achieve anti-inflammatory effects within human tissues may not be attainable via oral consumption.

Many studies on CLA in humans show a tendency for reduced body fat^[2], particularly abdominal fat, changes in serum total lipids and decreased whole body glucose uptake. Dietary CLA supplementation does not seem to have any adverse effects. The maximum reduction in body fat mass was achieved with a 3.4 g daily dose^[3].

CAS registry number: 2420-56-6, Molecular Formula: $C_{18}H_{32}O_2$

Contents

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Other benefits

CLA may be beneficial in other aspects, including prevention of breast and colon cancer, and prevention of insulin resistance and type II diabetes.

Dosage

CLA is available commercially in doses of about 500mg to 1000mg (or .5 g to 1 g). The optimal dosage is about 3.4 g, with larger doses showing little or no improvement.

CLA should be taken with food to prevent side effects, including diarrhea, nausea, and stomachache.

Dietary Sources

Kangaroo meat may have the highest concentration of CLA when compared with other foods. [1]

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(<http://www.csiro.au/index.asp?type=mediaRelease&id=kangaroofat>)

Food products of grass-fed ruminants (eg lamb, beef) are good sources, and contain much more CLA than those from grain-fed animals. [4]

References

1. ^ Lowery: Poison or Gift? 2001 International CLA Conference Report. (<http://forum.xtrememass.com/archive/index.php/t-323.html>)
2. ^ Thom E, Wadstein J, Gudmundsen O. (Sep-Oct 2001). "Conjugated linoleic acid reduces body fat in healthy exercising humans.". *The Journal of International Medical Research* 29 (5): 392-396. PMID 11725826 (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=11725826). Retrieved on 27 May 2006.
3. ^ Blankson H, Stakkestad JA, Fagertun H, Thom E, Wadstein J, Gudmundsen O. (December 2000). "Conjugated linoleic acid reduces body fat mass in overweight and obese humans." (<http://jn.nutrition.org/cgi/content/full/130/12/2943>). *Journal of Nutrition* 30 (12): 2943-2948. PMID 11110851 (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=11110851). Retrieved on 27 May 2006.
4. ^ T. R. Dhiman, L. D. Satter, M. W. Pariza, M. P. Galli, K. Albright, and M. X. Tolosa (May 2000). "Conjugated Linoleic Acid (CLA) Content of Milk from Cows Offered Diets Rich in Linoleic and Linolenic Acid" (<http://jds.fass.org/cgi/content/abstract/83/5/1016>). *Journal of Dairy Science* 83 (5): 1016-1027. PMID 10821577 (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=10821577). Retrieved on 27 May 2006.

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Categories: Fatty acids

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Linoleic acid

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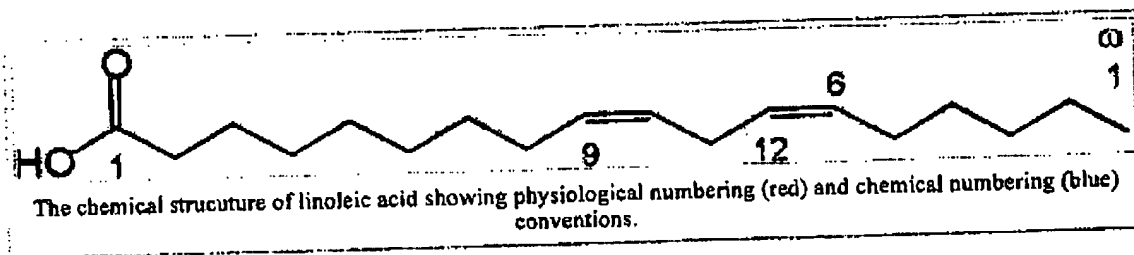
Linoleic acid (LA) is an unsaturated omega-6 fatty acid with the molecular formula $C_{18}H_{32}O_2$. It is a colorless liquid. In physiological literature, it is given the name 18:2(n-6). Its systematic chemical name is *cis, cis*-9,12-octadecadienoic acid. Chemically, linoleic acid is a carboxylic acid with an 18-carbon chain and two *cis* double bonds; the first double bond is located at the sixth carbon from the omega end. The structural formula is $CH_3-CH_2-CH_2-CH_2-CH=CH-CH_2-CH=CH-CH_2-CH_2-CH_2-CH_2-CH_2-COOH$. Linoleic acid has a molar mass of 280.44548(1724) g/mol.

The word *linoleic* comes from the Greek word *linon* (flax). *Oleic* means *of, relating to, or derived from oil or of or relating to oleic acid*.

Linoleic acid is a polyunsaturated fatty acid used in the biosynthesis of prostaglandins and cell membranes and in other natural oils. These oils include vegetable oil, especially sunflower oil.

To be fully utilised by the body, LA must be converted into gamma-linolenic acid, a reaction catalysed by the enzyme delta-6-desaturase (D6D).

Linoleic acid is used in making soaps, emulsifiers, and quick-drying oils. Reduction of linoleic acid yields linoleyl alcohol.



Linoleic acid is one of the two essential fatty acids that humans require. The other is alpha-linolenic acid. They are called "essential" because they can not be produced by the human body. Deficiency symptoms include dry hair, hair loss, and poor wound healing. Apparently, it is easy to meet the daily requirement for these fatty acids (even for people consuming low fat diets). Consuming approximately a tablespoon of polyunsaturated plant oils a day is sufficient. Essential fatty acids should not be confused with essential oils which are not required by the human body.

See also

- Omega-3 fatty acid
- Linolenic acid
- Essential fatty acids

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1. Beare-Rogers (2001). IUPAC Lexicon of Lipid Nutrition (<http://www.iupac.org/publications/pac/2001/pdf/7304x0685.pdf>). Retrieved on February 22, 2006. (in .pdf format)

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